



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

FEB 18 2009 4 7 '00 FEB 22 P1:42

The Honorable Jay Inslee  
House of Representatives  
Washington, DC 20515-4701

Dear Mr. Inslee,

Thank you for your letter of December 13, 1999, on behalf of your constituent, Mr. Grant Ramaley of Woodinville, Washington, regarding the US-European Union Mutual Recognition Agreement (MRA) for medical devices. The Food and Drug Administration (FDA or the Agency) appreciates the time that industry representatives take to voice their opinions on FDA matters. We welcome these comments and have forwarded them to the Docket Management Branch (Docket 98S-1064) for this matter where they will be considered by Agency officials in their decision making process on this issue.

We are enclosing materials on the MRA for pharmaceuticals and devices including congressional testimony and the final FDA regulation as background information.

We trust this information responds to your concerns. If you have further questions or comments, please contact us again.

Sincerely,

*Michael E. Plaisier*  
Melinda K. Plaisier  
Associate Commissioner  
for Legislation

Enclosure

cc: Docket Management Branch  
(Docket No. 98S-1064)

98S-1064

CI

1/ANS

JAY INSLEE  
1ST DISTRICT, WASHINGTON

COMMITTEE ON RESOURCES  
NATIONAL PARKS AND PUBLIC LANDS  
ENERGY AND MINERAL RESOURCES

COMMITTEE ON BANKING AND  
FINANCIAL SERVICES

FINANCIAL INSTITUTIONS AND  
CONSUMER CREDIT  
DOMESTIC AND INTERNATIONAL  
MONETARY POLICY

**Congress of the United States**  
**House of Representatives**  
Washington, DC 20515-4701

December 13, 1999

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Ms. Melinda Plaisier, Associate Commissioner  
Legislative Affairs  
Food and Drug Administration  
U.S. Department of Health and Human Services  
5600 Fishers Lane, Room 15-55  
Rockville, MD 20857

Dear Ms. Plaisier:

I am forwarding the e-mail of one of my constituents, Mr. Grant Ramaley. Mr. Ramaley is concerned about the Mutual Recognition Agreement being forged between the United States and the European Union.

I would appreciate if you could comment on Mr. Ramaley's e-mail and send the response to my Washington, DC office. I will relay your reply to Mr. Ramaley.

Should you have any questions, please do not hesitate to contact me. Thank you so much for your attention to this matter.

Very Truly Yours,

JAY INSLEE  
Member of Congress

JRI/jrs

Enclosure

99-7673

## Congressman Jay Inslee

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**From:** Web forms [webforms@www6.house.gov]  
**Sent:** Monday, November 29, 1999 6:01 PM  
**To:** Congressman Jay Inslee  
**Subject:** Email Jay Inslee

Name: Grant Ramaley - Aseptico Inc. - Regulatory Affairs  
Address: 8333 216th St. SE  
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Email: grant@aseptico.com  
FROM:  
Grant Ramaley  
Quality Assurance & Regulatory Affairs  
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8333 216th ST SE  
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E-MAIL grant@aseptico.com

I apologize for the length of this letter and its "E-structure".

> As you know, disastrous circumstances can  
> result when details in legislation are overlooked  
> and then implemented. Unfortunately, I have found  
similar flaws in the current Mutual Recognition Agreement being  
forged between the US and European Union regarding medical  
> device regulations. Its lacks appropriate  
> implementation and stands to result in billions  
> (affecting 80% of all medical products) of wasted  
> dollars on senseless regulatory waste. Waste that our  
> government originally and affectivity reduce in 1997  
> under the FDA modernization act. People at the FDA  
> have told me that only an act of legislation can change  
> the course of their activities. Please get this information  
> to knowledgeable legislators who are familiar with the  
> FDA Modernization Act. They will be shocked to learn what  
Ø I have. I am not attaching any files to alleviate any fear of viruses -  
Ø My explanations are as thorough and clear as I can make them.  
Ø I can provide further evidence as needed.

>  
> The Honorable  
>  
> United States House of Representatives  
> Washington, D.C. 20515.

>  
> Dear Senator or Congressperson,      November 24, 1999

>  
> I am employed by a dental manufacturer as a Quality Assurance and  
> Regulatory Affairs representative. I work closely with the FDA and  
> Foreign distributors. Our company is turning away from the benefits of  
> the FDA Modernization Act because of global changes for which the FDA is  
> largely involved.

>  
> I have been told by people in Washington not to tell you what I know.  
> What I am about to detail, explains some discoveries that I made while  
> comparing the medical device regulations of the FDA and Europe while  
> trying to understand the impact of the Mutual Recognition Agreement  
> (MRA) that both parties have signed and is in a late stage of  
> implementation. Some portions of the MRA between the US and Europe will

> be signed in mid December.

>

> The agreement, as I have learned, amounts to nothing that will benefit  
> either American manufacturers or consumers of medical devices and in  
> effect overrides the intentions of the FDA Modernization Act (FDAMA)  
> that the federal government concluded in 1997. In an age where medical  
> costs need to go down, the FDA has blatantly ignored its ability to help  
> assist and in effect has found a way around the FDAMA. The MRA between  
> Europe and the USA enforces costly duplication of surveillance audits  
> and imposes a re-classification of many medical devices that had been  
> earlier adopted by the FDAMA. The FDA argues that it is not responsible  
> for this since these regulations only affect companies who wish to  
> export to Europe. 40% of all medical devices are bought by Europe and  
> 40% are bought by the USA. The FDA is telling American manufacturers  
> to abandon sales in Europe if they do not wish to adopt the requirements  
> of the MRA. In affect we are being told by the FDA to conform to the  
> new European regulations or get out of Europe.

>

> To my horror, I have been told by the FDA offices at both the Center for  
> Device and Radiological Health and at the Division of Small  
> Manufacturers Assistance - Office of Health and Industry Programs that  
> there are several reasons US manufacturers are being ignored.

>

> 1) Expensive European Medical Device Regulation makes it too hard for  
> European Manufacturers to compete with US manufacturers. They want US  
> manufacturers to be similarly burdened (financially) to balance trade.

> 2) "The FDA does t have enough manpower to audit US firms"

> 3) The FDA officials working on the agreement are not being paid to do  
> so. "All work is conducted after hours" and they "don t have time to  
> listen" to me (manufacturers affected by the agreement) regarding the  
> obvious flaws and differences between the parties device classifications  
> (that are not addressed in the MRA).

> 4) Even though European and US audit guidelines are identical, the MRA  
> does not recognize the authority or determinations that the FDA makes  
> regarding compliance.

>

> I have to wonder why this MRA is even referred to as an "agreement".

> The only thing that it the US and E.U. "agree" on is that US medical  
> device manufacturers are too competitive and that US FDA audits findings  
> are meaningless. After this agreement goes into effect, U.S medical  
> device quality will be diminished as competition between smaller and  
> larger firms will squash those smaller firms who cannot afford the cost  
> of implementing regulation that the FDA had been forced to eliminate  
> under the FDAMA.

>

>

>

> I have done a very careful examination (paragraph by paragraph) review  
> and comparison of US regulation (21 CFR) and European Law (93/42/EEC).

> I can prove that every claim I am making is true. The FDA is not  
> helping consumers and manufacturers by signing the MRA as it is  
> currently expected to be implemented. The FDA is turning its back on  
> its responsibility to make health care better and affordable. The FDA  
> is not addressing it ability or responsibility to take a stand on issues  
> pertaining to the classification of devices and the authority of their  
> own surveillance activity determinations.

>

> In 1997 the E.U. implemented the medical device directive 93/42/EEC.

> The UK alone spent 500 million adopting the changes. Most of these  
> burdens are carried by the manufacturers and then the citizens who are  
> forced to buy properly "marked" equipment. Imagine the cost to US  
> manufacturers and its citizens when the MRA (as it currently stands)

- > goes into effect. The FDAMA will be squashed and the MRA's power
- > (affecting 80% of the world market) will begin to re-shape medical
- > device regulations in a manner that will certainly hurt
- > anyone trying to compete with those who can afford the cost of
- > implementing it.
- >
- > I do not imagine that you can fully grasp the magnitude and scope of the
- > horrible burden that is overtaking the global medical device community
- > since it usually takes about a 30 to 40 minute phone call to substantiate
- > these claims with people who think they know this industry's laws. Only
- > medical device experts who are familiar with the MRA are completely
- > aware of what is going on. These stakeholders are all crafting this
- > agreement to address their personal needs and not the needs of industry
- > or people.
- >
- > I stumbled on this because I am one of the few who have relied on the
- > FDA to be my advocate for certifying our products to foreign
- > government. I am well versed in US and European Medical Device
- > regulation and am one of the most knowledgeable people you'll find
- > regarding the impact of the MRA on industries like our dental industry.
- >
- > I am attaching a bunch of pieces of the evidence that asserts my
- > findings. When you finally realize what is being done by the FDA with
- > regard to the MRA, you will feel like you are awakening into a horrible
- > nightmare. I apologize for that. I believe there is still time to
- > address these issues. I have been told that "only an act of
- > legislation" can change the course of action that is coming. I have
- > been told by some in Washington DC not to tell you what I've learned. I
- > believe there is still time to stop the FDA from implementing an MRA
- > that allows large portions of the FDA MA to be destroyed.
- >
- > Please let me know if I can help you. I feel a moral obligation to
- > assist you.

> Kind regards

>  
 Grant Ramaley  
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